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10/821.626

04/09/2004

Michael G. Mulkerrin

ABGENIX.043A

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07/28/2006

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,626

Applicant(s)

MULKERRIN ET AL.

Examiner

Charles L. Patterson, Jr.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 59 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 16-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-15 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Group III, claims 5-15 in the reply filed on 6/20/06 is acknowledged.

Claims 1-4 and 16-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/20/06. Claims 1-15 and 59 will be examined.

The disclosure is objected to because of the following informalities:

In paragraph 48, reference is made to Figure 1 and 2. There are no figures in the instant application.

Appropriate correction is required.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is confusing because it is dependent upon claim 1, which claim was not elected for prosecution.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-15 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discusses making antibodies in general and discloses a method of making the compound shown in claim 1. There is no disclosure that the antigen made has ever been used to make antibodies and especially not catalytic antibodies. Therefore one of ordinary skill in the art would not have conveyed to them that at the time the application was filed, applicant had in his possession a catalytic antibody of the instant claims.

Claims 5-15 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As discussed *supra*, the instant specification does not disclose that any antibodies have been made using the structure shown in claim 1 as the antigen and certainly does not disclose that any antibodies that were catalytic have been made. While it is acknowledged that most chemical compounds can be used to make an antibody, especially if it is attached to a carrier molecule, the making of antibodies that are catalytic is an unpredictable art. Whether an antibody is catalytic or not depends upon the identity of the antigen used to make it. This has been shown to be unpredictable.

Janda, et. al. (U), Schultz (A), Sinha, et al. (B) and Yu, et al. (V) are cited in this regard. In Janda, catalytic antibodies were raised against hapten (1) and it was found that substrates with the greatest homology to the hapten (2 and 3) were not hydrolyzed appreciably by the antibody, whereas substrates that had less homology to the hapten (4-6) were hydrolyzed. In

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Schultz, a catalytic antibody raised against a mixture of diastereomers of a hapten (I) catalyzed the cleavage of a homologous substrate (II) but only the D diastereomer, not the L diastereomer, even though the hapten was a mixture of diastereomers. In Sinha, et al. the hapten used to make the antibodies (Fig. 4) had essentially no resemblance to the reactants or products of the reaction catalyzed (Fig. 1). In Yu, et al. twenty-nine different antibodies were made against a close analog of a substrate and none of them had catalytic activity (see column 2, page 340). As discussed by Tawfik, et al. (W) on pages 91-92, most catalytic antibody activity (in 1994) "is still very modest" compared with enzymes. "[T]he nature of all of the reported antibody-catalyzed reactions is such that they proceed with measurable rates even in the absence of any catalyst". "Most of the antibody catalyzed hydrolytic reactions involve esters, and in particular phenyl esters (that are relatively labile)....The hydrolysis of amides, that are orders of magnitude more stable than esters, was demonstrated only when activated amide substrates were used or when intramolecular deamidation could occur...or by utilizing the chemical reactivity of a metal complex".


It is maintained that undue experimentation would be required to make the catalytic antibodies of the instant claims. There is absolutely no indication that the antigen in claim 1 has been used to make any antibodies and certainly not that the antibodies have any catalytic activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
July 24, 2006